

**STATE OF MICHIGAN**  
**DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS**  
**OFFICE OF FINANCIAL AND INSURANCE REGULATION**  
**Before the Commissioner of Financial and Insurance Regulation**

**In the matter of**

**XXXXXX**

**Petitioner**

**v**

**File No. 121984-001**

**Blue Cross Blue Shield of Michigan**  
**Respondent**

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**Issued and entered**  
**this 28th day of September 2011**  
**by R. Kevin Clinton**  
**Commissioner**

**ORDER**

**I. Procedural Background**

On June 21, 2011 XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the material submitted and accepted the request on June 28, 2011.

The Petitioner receives health care benefits through her employer, XXXXX, under a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Petitioner's benefits are described in BCBSM's *Preferred RX Program Certificate*.

To address the medical issues in the case, the Commissioner assigned the case to an independent medical review organization which provided its analysis and recommendation to the Commissioner on July 12, 2011. (A copy of the complete report is provided to the parties with this Order.)

**II. Factual Background**

Petitioner was diagnosed with a mild case of multiple sclerosis in 2007 and was prescribed the drug Avonex. In March 2011, her doctor prescribed the drug Betaseron. BCBSM denied coverage for Betaseron claiming that a suitable alternative drug could have been used.

The Petitioner appealed the denial through BCBSM's internal grievance process but BCBSM did not change its decision. BCBSM issued a final adverse determination dated May 13, 2011.

### **III. Issue**

Did BCBSM properly deny coverage for Betaseron under the terms of the certificate?

### **IV. Analysis**

#### **BCBSM's Argument**

Section 2 of the certificate under "Covered Drugs Obtained from A Panel Pharmacy" it states, in part:

Certain drugs may not be covered for a second prescription if a suitable alternate drug is identified by BCBSM (either a comparable brand, generic or over-the-counter drug), unless the prescribing physician demonstrates that the drug is medically necessary. . . .

It is BCBSM's position that the Petitioner has not yet met the necessary criterion for prior authorization of Betaseron. The Petitioner would like BCBSM to cover this prescription because Betaseron has an injector that assists with injecting, whereas the formulary alternative, Extavia, does not.

BCBSM states, that while Betaseron might be more convenient, there is no documentation indicating that Extavia was either contraindicated or tried and failed. There is no information provided to confirm the Petitioner's intolerance to Extavia, which is an interferon Beta 1-b product, like Betaseron. Therefore, prior authorization was denied.

#### **Petitioner's Argument**

The Petitioner states that in March 2011 she asked her doctor for another treatment for her multiple sclerosis. He recommended Betaseron instead of Extavia. She has been taking Betaseron since April 23, 2011.

The Petitioner indicates that her research shows that Betaseron and Extavia are very similar. The only difference is Extavia has a 27-gauge needle which is larger and does not have an injector. Betaseron has a 30-gauge needle which is smaller and has an injector. The Petitioner argues that she needs assistance with the injection. With the injector she can do it herself; without it she would need someone like a nurse to assist with her every other day injections. If she uses manual injections with Extavia her treatment would not be as regular as with the Betaseron with the injector.

Therefore, the Petitioner believes that Betaseron is medically necessary for treatment of her condition and BCBSM is required to preauthorize and cover it.

### Commissioner's Review

The question of whether Betaseron was medically necessary was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act. The IRO reviewer is a physician in who has been in active clinical practice, is certified by the American Board of Psychiatry & Neurology with subspecialty certification in neurology and clinical neurophysiology. The reviewer is a clinical professor in neurology, and is a director of an electrophysiology monitoring program. The reviewer determined that the medication Betaseron is not medically necessary for treatment of the Petitioner's condition. The IRO report includes the following comments and conclusions:

Interferon B (IFN B) is medically necessary for the enrollee's treatment and Betaseron is a drug within this category of medications. However, there is an equivalent brand name drug available on the formulary. There is no documentation that the patient has tried this formulary medication. Also of note, there is no known clinical efficacy difference between Betaseron and the drug which is the formulary equivalent.

\* \* \*

The enrollee is concerned that without the injector she may not be able to self inject. However, she has not tried the formulation without the injector. With education and training with a nurse, she may be able to accomplish this safely.

There is no compelling evidence provided that the formulary medication has been trialed and failed. There is no clinical rationale or evidence provided to establish Betaseron as a more efficacious medication for this clinical scenario. Convenience issues or an unwillingness to be trained in self-injection do not comprise medical necessity.

### **Recommendation:**

It is the recommendation of this reviewer that the denial of coverage issued by Blue Cross and Blue Shield of Michigan for the medication Betaseron be upheld.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principle reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

### **V. Order**

The Commissioner finds that Blue Cross Blue Shield of Michigan is not required to prior authorize and cover the Petitioner's Betaseron prescription. BCBSM's May 13, 2011, final adverse determination is upheld.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.